

510(K) Summary

JAN 21 2010

**N.M.B. Medical Applications, Ltd.
Quantum IM Composite Nailing System**

Applicant Name

N.M.B. Medical Applications, Ltd.
11 Ha'hoshlim St., Herzeliya 46724, Israel

Contact Person

1. Yael Rubin

N.M.B. Medical Applications, Ltd.
11 Ha'hoshlim St., Herzliya 46724, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

2. Jonathan S. Kahan, Esq.

Hogan & Hartson LLP
555 Thirteenth Street, NW, Washington, DC 20004, U.S.A.
Tel: 202-637-5794, Fax: 202-637-5910

Date Prepared

October 2009

Trade/Proprietary Name

Quantum IM Composite Nailing System (Quantum Nailing System)

Common Name

Intramedullary Nailing System

Classification Name

Rod, Fixation, Intramedullary and Accessories (21 CFR §888.3020; Product Code HSB)

Predicate Devices

Intended Use/Design/Technology/Operation

- UHN Humeral Nailing System (Synthes; K933518)
- Fixion® Interlocking Intramedullary Nailing System (N.M.B. Medical Applications, Ltd.; K002783, K013449, K032588)
- Intramedullary Nail System (Smith & Nephew, Inc.; K983942)

Material

- KIMBA™ Spinal Implant (SIGNUS Medizintechnik GmbH; K052533)
- Spine-Tech™ Cement Restrictor (Centerpulse, Spine-Tech Division; K022615)
- Stackable Cage System (DePuy Spine, Inc.; K073649)
- Fixion® DHS System (N.M.B. Medical Applications, Ltd.; K031401)

Intended Use/Indications for Use

Indications for the Quantum IM Composite Humeral Nail include simple humeral fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Quantum IM Composite Humeral Nail is indicated for fixation of fractures that occur in and between the proximal and distal third of the humerus.

System Description

The Quantum IM Composite Nailing System includes nails, interlocking screws and a set of instruments.

The Quantum IM Composite Nail is a cylindrical solid rod, made of carbon fiber reinforced polymer. Its diameter ranges from 7 to 8.5 mm, with lengths in the range of 180 to 280 mm. The nail provides for holes at its proximal and distal sections, designed for the insertion of the 3.5 mm self-tapping, cortical, titanium-alloy-made, interlocking screws. The nail has a closed, pointed distal end, and its proximal end incorporates a thread enabling connection of insertion/extraction instrumentation.

Substantial Equivalence

The Quantum IM Composite Nailing System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Performance characteristics, evaluated per ASTM F 1264, are also comparable to those of predicate devices, thus demonstrating that the device is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

N.M.B. Medical Applications, Ltd.
% Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson LLP
555 Thirteenth Street, North West
Washington, District of Columbia 20004

JAN 21 2010

Re: K091425

Trade/Device Name: Quantum IM Composite Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: November 30, 2009
Received: December 3, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Jonathan S. Kahan

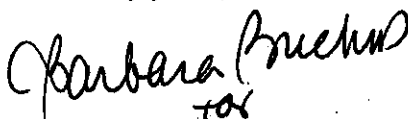
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Bruch" with a small "for" written below it.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

N.M.B. Medical Applications, Ltd.
Quantum IM Composite Nailing System

K091425

Indications for Use

510(K) Number (if known): K091425

Device Name: Quantum IM Composite Nailing System (Quantum Nailing System)

Indication for Use:

Indications for the Quantum IM Composite Humeral Nail include simple humeral fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Quantum IM Composite Humeral Nail is indicated for fixation of fractures that occur in and between the proximal and distal third of the humerus.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091425